

REMARKS

Claims 1-66 were pending in the present application prior to entry of the present amendment. Claims 3, 4, 12-55, 58, and 59 were previously withdrawn from consideration as drawn to a non-elected invention. By virtue of this response, claims 8 and 56-66 have been cancelled, without prejudice; claim 1 has been amended; and new claims 67-69 have been added. Support for the amendment to claim 1 can be found at least at page 6, lines 21-24 and support for new claims 67-69 can be found at least at page 23, lines 10-27 and page 28, lines 3-13. Accordingly, claims 1-2, 5-7, 9-11, 67-69 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicants reserve the right to prosecute amended or cancelled subject matter in related applications. Applicants request rejoinder of methods claims to the extent they recite all the limitations of allowed composition claims. See in re Ochiai.

Applicants gratefully acknowledge that the Section 102(b) rejection of claims in view of Schwartz et al. and the Section 102(e) rejection of claims in view of Schwartz et al. have been withdrawn. Applicants gratefully acknowledge that the Section 102(e) rejection of claims 56, 57, and 60-66 in view of Raz et al. has been withdrawn.

MPEP 707.02

This application was filed March 9, 2001 and therefore has been pending *almost* five years. The instant Office Action is the fifth Office Action (not including the Restriction Requirements) mailed by the USPTO in the file history. MPEP 707.02¹ states that any application that has been pending five years should be carefully studied by the supervisory patent examiner and every effort should be made to terminate its prosecution. Pursuant to MPEP 707.02, Applicants request that the Supervisory examiner, Andrew Wang, review this application with a view to finally concluding its prosecution. MPEP 707.02 states that to accomplish this result, the application is to

¹ Applications up for third action and 5-year applications.

be considered “special” by the examiner. Applicants request that the examiner consider this application as “special” due to the length of its pendency and the number of Office Actions mailed.

Rejection of Claims Under 35 U.S.C. 102(e)

Claims 1, 2, and 5-11 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Raz et al. for the reasons set forth in the Office Action mailed April 12, 2005. Applicants note that MPEP 707.02 states that the shortest path to the final disposition of an application is by finding the best references on the first search and carefully applying them. Raz et al. was not applied by the Examiner in this Section 102(e) rejection until the 4th Office Action.

Applicants traverse this rejection of claims. In order for a reference to anticipate a claim, each and every element of the claimed invention must be found in the reference. Claim 1 recites a pharmaceutical composition, comprising: an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, comprising: a polynucleotide comprising an immunostimulatory sequence (ISS) linked to the surface of a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5'-C, G-3', and wherein said microcarrier is less than about 10 μ m in size, with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin, wherein the complex is antigen free; and a pharmaceutically acceptable carrier. Raz does not identically disclose or describe, within the meaning of 102, the claimed invention. Raz has no specific disclosure or description of the claimed pharmaceutical composition, claimed kits or methods of using them.

The Examiner at pages 2-3 alleges that Raz et al. teaches the claimed invention and directs Applicants attention to the abstract (which has no disclosure of the claimed compositions comprising IMP/MC complexes); col. 14, lines 50-67 (which have disclosure directed to compositions comprising ISS, an antigen and an adjuvant and have no disclosure of the claimed compositions); col. 15, lines 31-41 (which have general disclosure regarding effective amounts of components and have no specific disclosure of the claimed compositions); col. 17, lines 10-28 (which have general disclosure of polymers and have no specific disclosure of the claimed compositions); col. 20, lines 61-col. 21, line 46 (which provide general discussion of platform

molecules which contain sites for ISS and antigen and have no specific disclosure of the claimed compositions); and col. 27, lines 19-36 (which contain general disclosure regarding administration of ISS and have no specific disclosure of the claimed compositions).

The Examiner at page 3 of the Office Action alleges that the Raz et al. patent is not limited to encapsulated microparticles and/or liposomes, and refers to col. 16, lines 34-36. Raz et al. col. 16, lines 34-36 disclose that an ISS and antigen are proximately associated by adsorption onto a surface. Claim 1 recites, in part, a pharmaceutical composition that comprises an IMP/MC complex wherein the complex is linked to the surface of a nonbiodegradable MC and wherein the complex is antigen free. The Examiner alleges that Raz et al. teaches the covalent linkage of non-encapsulated ISS oligonucleotides to platform molecules, including on the surface of platform molecules and refers to col. 16, lines 32-41 (which disclosure relates to the association of ISS with antigen) and col. 20-col. 21 (which disclosure generally relates to platform molecules). None of the Raz et al. disclosures referenced by the Examiner provide a specific teaching of the claimed invention.

The Examiner alleges that the sizes recited in the claims, that is a microcarrier less than about 10 μ m in size, fall within the disclosure of Raz et al. at col. 21, lines 3-24 which disclose, in part, that i. platform molecules generally have a molecular weight in the range of about 200 to about 200,000 and ii. preferred polymers are based on PEG having a molecular weight of about 200 to about 8000. With respect to the molecular weight range disclosed in Raz et al., the Examiner states at page 4 of the Office Action that the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product. As discussed above, Raz et al. has no specific teachings regarding the claimed invention and the claimed invention does not necessarily flow from Raz et al. The claimed invention, which recites, in part, an IMP/MC complex that is antigen free wherein the microcarrier is less than about 10 μ m in size, does not necessarily flow from a teaching that i. platform molecules generally have a molecular weight in the range of about 200 to about 200,000 and ii. preferred polymers are based on PEG having a molecular weight of about 200 to about 8000.

In view of the above, Applicants submit that Raz et al. does not anticipate the claimed invention. Applicants respectfully request withdrawal of this rejection of claims.

Rejection of Claims Under 35 U.S.C. 112, First Paragraph

Claims 56, 57, and 60-65 stand rejected under 35 U.S.C. 112, first paragraph, allegedly because the specification, while being enabling for the *in vitro* immunomodulation of mouse splenocytes and human PMN cells using the IMP/MC complexes of examples 1-4 of the instant specification, does not reasonably provide enablement for compositions and instructions to use any nonbiodegradable IMP/MC complexes for administration and immunomodulation in an individual.

Applicants traverse this rejection. For the record, Applicants note that in the Office Action mailed April 20, 2004, the Examiner rejected claims 56-66 under 35 U.S.C. 112, first paragraph enablement on these same grounds. Applicants mailed a response to this rejection September 20, 2004 and the Examiner specifically withdrew this rejection in the next Office Action mailed April 12, 2005. Therefore, Applicants have overcome this rejection in the previous file history.

The arguments provided in the September 20, 2004 response regarding the Section 112, first paragraph enablement rejection are reiterated here. Thus, Applicants respectfully submit that a *prima facie* case of lack of enablement has not been established. Accordingly, the pending claims are in compliance with the enablement requirements.

Without acquiescing to this rejection and solely in an effort to expedite prosecution, Applicants have cancelled claims 56-66, thereby obviating this rejection of claims. Applicants request withdrawal of this Section 112, first paragraph, enablement rejection of claims.


CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 377882001700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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